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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/524,101

03/13/2000

Andrew Roy Buchman

EX00-015

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06/20/2003

JAN P. BRUNELLE

EXELIXIS, INC.

170 HARBOR WAY

P.O. BOX 511

SOUTH SAN FRANCISCO, CA 94083-0511

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,101

Applicant(s)

BUCHMAN ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,7 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4,7 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed 6/5/03; 4/7/03. Currently, claims 2-4, 7, 11-13 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
3. This action contains new grounds of rejection necessitated by amendment.
4. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims and the applicants' remarks.

Election/Restrictions

5. Applicant's election without traverse of Group 1, SEQ ID NO: 1 and 2 (*Drosophila* p53 is acknowledged.

Claims containing SEQ ID NO: 3-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

It is noted that the original restriction requirement indicated that there was no generic claim. Therefore, the nucleic acids are independent and distinct. No further search will be performed to evaluate SEQ ID NO: 3-10 upon determination of allowable subject matter directed to SEQ ID NO: 1-2. Since SEQ ID NO: 28 and 32 are subfragments of SEQ ID NO: 2, SEQ ID NO: 28 and 32 have been examined.

The requirement is still deemed proper and is therefore made FINAL.

Priority

6. This application claims priority as continuation-in-part of U.S. application no. 09/268,969, filed March 16, 1999, and of U.S. application no. 60/184,373, filed February 23, 2000.

Drawings

7. The drawings contain holes in the drawings which overlap the text of the drawings. Submission of formal drawings is required prior to allowance.
8. The drawings contain sequences which are not identified by SEQ ID NO: in either the drawing or the brief description of the drawings.

Specification

9. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 59, for example, contains a hyperlink.

10. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Newly amended Claims 2-4, 7, 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to an isolated nucleic acid molecule that encodes a polypeptide which comprises an amino acid sequence selected from SEQ ID NO: 28 and 32. The claims also requires that the nucleic acid molecules that encodes a polypeptides is either an insect p53 polypeptide, a dominant negative form of said insect p53 polypeptide, a constitutively active form of said insect p53 polypeptides and a domain of said insect p53 molecule.

The specification teaches a single Drosophila insect p53 molecules (DMp53), namely SEQ ID NO: 1 which encodes a polypeptide of SEQ ID NO: 2. The specification has performed functional analysis of the DMp53 nucleic acid (page 55).

The description in the specification as filed is not sufficient to convey that the applicant was, as of the filing date, in possession of the invention in a manner commensurate in scope with the claims. There is disclosed only a limited number of species, and applicants attempt to claim, on the basis of that single species, any isolated nucleic acid that encodes a polypeptide comprising SEQ ID NO: 28 or 32. Given this broad definition, the scope of the claims would appear to be much broader

than the particularly disclose species, and one is unable to envision, and the specification does not adequately describe, a commensurate number of species.

Claim 4 broadly encompasses any nucleic acid molecule that encodes a polypeptide comprising SEQ ID NO: 28 or 32. The claim encompass genomic *Drosophila* p53, mutants, variants, homologs and splice variants which have not been described and are yet to be discovered. The disclosed structural feature of SEQ ID NO: 28 and 32 does not constitute a substantial portion of the claimed genus. The claim recites many polypeptides which have not been described. Moreover, the claim recites numerous domains which have not been described. There is no actual reduction to practice of the claimed invention, clear depiction of the claimed invention in the drawings or completed description of the structure. Considering all disclosed distinguishing identifying characteristics, there is a disclosure of partial structure. However, there is no known or disclosed correlation between a function and the structure of the claimed invention. Weighing all factors, 1) partial structure of the DNAs which comprise SEQ ID NO; 28 and 32, 2) the breadth of the claim as reading on genomic DNA, mutant, variants, homologs yet to be discovered, 3) the lack of correlation between the structure and the function of the genes; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of nucleic acids which comprise SEQ ID NO: 28 or 32.

Further, Claim 3 is directed to an isolated nucleic acid molecule that hybridizes under stringent hybridization conditions to SEQ ID NO: 1. Unlike Example 9 in the

Written Description Guidelines, the claim does not contain any specific function. A person of skill in the art would expect substantial variation among species encompassed within the scope of the claims because stringent hybridization conditions to a partial nucleic acid would yield structurally dissimilar DNAs.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention*. The invention is, for the purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NO: 1 and 2 referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Fevel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only nucleic acids of SEQ ID NO: 1 and encoding SEQ ID NO: 2 but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

Allowable Subject Matter

12. Claims drawn to a nucleic acid comprising SEQ ID NO: 1 and a nucleic acid encoding SEQ ID NO: 2 would be allowable. The art neither teaches nor suggests a nucleic acid comprising SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2.

Conclusion

13. **No claims allowable over the art.**

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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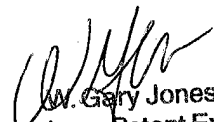
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
June 17, 2003


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600